

WHAT IS CLAIMED IS:

1 1. A catheter for removing material from a body lumen, said catheter
2 comprising:
3 a catheter body having a proximal end and a distal end;
4 a material capture device arranged on said catheter body to engage said
5 material; and
6 a cutting element mounted near the distal end of the catheter body to move
7 between a first position and a second position to cut said material while said material is
8 engaged by said material capture device, wherein motion of the cutting element urges the
9 material capture device to draw cut material into the catheter body.

1 2. A catheter as in claim 1 wherein said catheter body comprises a
2 proximal, flexible portion and a distal, rigid portion containing said cutting element.

1 3. A catheter as in claim 2 wherein said catheter body comprises a
2 inner cutter mounted coaxially within said distal, rigid portion, said material capture
3 device mounted on said inner cutter.

1 4. A catheter as in claim 2 wherein said catheter body comprises an
2 atraumatic distal tip mounted on said distal, rigid portion.

1 5. A catheter as in claim 1 wherein:
2 said material capture device is arranged on said catheter body to advance
3 along a path outwardly from the catheter body into said material and then inwardly
4 towards the catheter body to tension said material; and
5 said cutting element on said catheter body moving between said first
6 position and said second position to cut said material while in tension.

1 6. A catheter as in claim 5 wherein said path comprises a radially
2 curved path extending in an outward direction away from the catheter body towards said
3 material to be cut off.

1 7. A catheter as in claim 6 wherein said material capture device
2 moving along said path does not exceed the outer diameter of the catheter body.

09916642-072701

1 8. A catheter as in claim 5 wherein said material capture device
2 travels in a slot on the catheter body to advance along said path.

1 9. A catheter as in claim 5 wherein said material capture device
2 travels in a groove on the catheter body to advance along said path.

1 10. A catheter as in claim 5 wherein said material capture device
2 comprises a bias element to urge said material capture device along said path.

1 11. A catheter as in claim 5 wherein said material capture device is
2 configured to rotate about a pivot pin to deploy said material capture device along said
3 path.

1 12. A catheter as in claim 1 wherein said material capture device
2 comprises:
3 a penetrating member pivotably mounted about a pin on said cutting blade,
4 said penetrating member movable between a first, tissue-engaging position and a second
5 tissue-retracting position; and
6 a cam surface disposed on said catheter body to contact and rotate said
7 penetrating member about said pivot point when said cutting blade is advanced over the
8 cam surface.

1 13. A catheter as in claim 12 wherein said cam surface is configured to
2 slidably contact a lower surface on said penetrating member to guide said penetrating
3 member over an accurate path as the cutting blade is advanced.

1 14. A catheter as in claim 13 wherein said cam surface includes a
2 groove for mating with said penetrating member.

1 15. A catheter as in claim 13 wherein said cam surface includes a first
2 groove having a funneled opening and a second groove having a second funneled
3 opening.

1 16. A catheter as in claim 13 wherein said penetrating member
2 comprises a recess on said lower surface to facilitate positioning of said member over said
3 cam surface.

09916542-072701

1 17. A catheter as in claim 1 wherein said material capture device
2 comprises:

3 a penetrating member rotatably mounted on said cutting element; and
4 an abutment disposed on said catheter body to engage one end of the
5 penetrable member and cause rotation of the penetrating member from a first, open
6 position to a second, closed position.

1 18. A catheter as in claim 17 further comprising a tether coupled to
2 said penetrating member to control positioning of the penetrating member.

1 19. A catheter as in claim 1 wherein said material capture device
2 comprises a penetrating member rotatably mounted on said catheter body and fixedly
3 secured relative to said slidable cutting element;

4 a pushing element mounted on said cutting element to engage said
5 penetrating member to move said member between a first position to a second tissue-
6 engaging position.

1 20. A catheter as in claim 1 wherein said material capture device is
2 configured to be deployed from an aperture in the side wall of the catheter body.

1 21. A catheter as in claim 20 wherein said cutting element includes an
2 material imaging device mounted to be in an imaging position when said aperture is
3 closed by said cutting element.

1 22. A catheter as in claim 1 wherein said cutting element includes a
2 first cutting blade having at least one penetrating point.

1 23. A catheter as in claim 1 wherein said cutting element has a first
2 cutting blade opposed to a second cutting blade for removing said material.

1 24. A catheter as in claim 1 wherein said cutting element comprises a
2 tubular inner cutter slidably mounted within an outer cutter of the catheter body, said
3 inner cutter coupled to a drive wire actuated by a user.

0916642.072701

1 25. A catheter as in claim 1 wherein said material capture device
2 extends an extension distance outward from the catheter body to engage material, said
3 extension distance equal to the diameter of the catheter body.

1 26. A catheter as in claim 1 wherein said material capture device
2 includes a barbed distal tip to retain material on the capture device.

1 27. A catheter as in claim 1 wherein said cutting element further
2 comprises a material imaging device.

1 28. A catheter as in claim 27 wherein said material imaging device
2 comprises an ultrasound transducer array.

1 29. A catheter as in claim 1 wherein said material capture device
2 comprises means for penetrating said material.

1 30. A catheter as in claim 29 wherein said means for penetrating
2 material comprises a curved needle biased outwardly from the catheter body.

1 31. A catheter as in claim 29 wherein said means for penetrating
2 material comprises a penetrating member rotatably mounted about a pivot pin on said
3 cutting element.

1 32. A catheter as in claim 29 wherein said means for penetrating
2 material is configured to engage a raised portion on said catheter body to move said
3 means to engage material and then retract material into the catheter body.

1 33. A catheter as in claim 32 wherein said raised portion comprises a
2 cam surface having a plurality of tracks, wherein each track has a funneled entrance to
3 guide said penetrating member therein.

1 34. A catheter for removing material from the wall of a body lumen,
2 said catheter comprising:
3 a catheter body having a proximal end and a distal end;
4 a side aperture on the catheter body;
5 a cutting blade adapted to advance past the aperture to sever material
6 which intrudes through the aperture; and

09916642.072701

a penetration member mounted to extend through the aperture to penetrate material in advance of the cutting blade and to draw material into the catheter body as the cutting blade is advanced past the aperture.

35. A catheter as in claim 34 further comprising a cam surface mounted on said catheter body, said cam surface having a surface configured to guide said penetration member into said material when said blade is advanced.

36. A catheter for removing material from a body lumen, said catheter comprising:

a catheter body having a proximal end and a distal end;

a material capture device arranged on said catheter body to advance along a path radially outwardly from the catheter body into said material and then inwardly towards the catheter body to tension said material; and

a cutting element on said catheter body moving between a first position and a second position to cut said material while said material is in tension.

37. A catheter for removing material from a body lumen, said catheter comprising:

a catheter body having a proximal end, a distal end, and an aperture;

a slidable, telescoping portion on said catheter body configured to extend outwardly from said aperture on the catheter body, said telescoping portion having a first open position leaving a gap between one edge of said portion and said catheter body to define a cutter window in which material may intrude to be engaged and having a second closed position wherein said cutting blade is positioned to cut off said material.

38. A catheter as in claim 37 wherein said gap defines a side-opening cutter window.

39. A catheter as in claim 37 wherein said aperture comprises a forward facing, distal aperture on the catheter body.

40. A catheter as in claim 37 further comprising a material capture device mounted on said telescoping portion, said portion moving between a first position and a second position to cut said material while said material is engaged by said material

09916642-072701

4 capture device, wherein motion of the telescoping portion urges the material capture
5 device to draw cut material into the catheter body.

1 41. A catheter as in claim 40 wherein said material capture device is
2 rotatably mounted to said telescoping portion and configured to engage a raised portion
3 on said catheter body to rotate said material capture device to engage material and then
4 draw material into the catheter body.

1 42. A method for excising occlusive material from within a body
2 lumen, said method comprising:
3 capturing said occlusive material with a material capture device on a
4 catheter body;
5 drawing said device radially inwardly towards the catheter body to tension
6 the material; and
7 advancing a blade through the tensioned material to sever said material
8 from the body lumen.

1 43. A method as in claim 42 wherein said engaging of said occlusive
2 material comprises extending said material capture device from said catheter body in a
3 radially outward direction.

1 44. A method as in claim 43 wherein said material capture device does
2 not extend beyond the outer diameter of the catheter body when engaging said material.

1 45. A method as in claim 42 wherein said engaging of said occlusive
2 material comprises penetrating said material with said material capture device.

1 46. A method as in claim 42 wherein said engaging of occlusive
2 material comprises radially extending said material capture device outward from an
3 aperture on the catheter body.

1 47. A method as in claim 46 wherein said engaging of said occlusive
2 material comprises guiding said material capture device against a raised portion on the
3 catheter body to direct said capture device into said material.

00916642.072701

1 48. A method as in claim 46 wherein said engaging of said occlusive
2 material comprises advancing said cutting blade to engage a pushing element against said
3 material capture device mounted on the catheter body.

1 49. A method as in claim 46 wherein said engaging of said occlusive
2 material comprises penetrating said material in advance of the blade and said drawing of
3 said device into the catheter body occurs as the cutting blade is advanced past the
4 aperture.

1 50. A method as in claim 46 further comprising imaging said material
2 prior to cutting said material, wherein said imaging occurs when said aperture is closed
3 by said cutting blade.

1 51. A method as in claim 42 wherein said drawing of the device
2 comprises moving said material capture device radially towards said catheter body while
3 said material capture device remains in contact with said material.

1 52. A method as in claim 51 wherein said drawing of said material
2 capture device occurs when said cutting element is advanced, said cutting element
3 pushing against said material capture device and biasing it into the catheter body.

1 53. A method as in claim 51 wherein drawing of said material capture
2 device comprises positioning said material capture device against a raised portion on the
3 catheter body to guide said device with the material into the catheter body.

1 54. A method as in claim 42 wherein said engaging and tensioning of
2 material are performed through a single motion by the user.

1 55. A method for removing material from a body lumen, said method
2 comprising:
3 positioning a catheter within the lumen;
4 extending a distal portion of the catheter forwardly to open an aperture,
5 wherein material is invaginated into the aperture; and
6 closing the distal portion of the catheter to close the aperture and sever the
7 invaginated material.

09916642 " 072701

1 56. A method as in claim 55, wherein the body lumen is a blood vessel
2 and the material is atheromatous material.

1 57. A method as in claim 55, further comprising penetrating the tissue
2 with a material capture device and drawing the captured material into the aperture with
3 the device as the distal portion of the catheter body is closed.

1 58. A kit comprising:
2 a catheter having a material capture device and a cutting element;
3 instructions for use in removing material from a body lumen comprising
4 engaging said material with a material capture device and tensioning said material
5 towards the catheter while cutting said occlusive material with a cutting element; and
6 a package adapted to contain the device and the instructions for use.

ADD
A1

0916642-072701